



U.S. ENVIRONMENTAL PROTECTION AGENCY
 Office of Pesticide Programs
 Antimicrobials Division (7510P)
 1200 Pennsylvania Ave., N.W.
 Washington, D.C. 20460

EPA Reg. Number:

211-65

Date of Issuance:

12/16/19

NOTICE OF PESTICIDE:

Registration
 Reregistration
 (under FIFRA, as amended)

Term of Issuance:

Conditional

Name of Pesticide Product:

TRI-CEN

Name and Address of Registrant (include ZIP Code): SENT TO:

Central Solutions, Inc.
 401 Funston Road
 Kansas City, KS 66115

Heather Bjornson-Lam
 Senior Regulatory Consultant
 Agent for Central Solutions, Inc.
 c/o Bjornson Regulatory Consulting LLC
 272 Hathaway Lane
 Wynnewood, PA 19096

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Antimicrobials Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A). You must comply with the following conditions:

1. Submit and/or cite all data required for registration/reregistration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

Signature of Approving Official:

Jacqueline Hardy, Product Manager 34
 Regulatory Branch II, Antimicrobials Division (7510P)
 Antimicrobials Division (7510P)

Date:

12/16/19

2. You are required to comply with the data requirements described in the DCI identified below:
 - a. o-phenylphenol: GDCI-64103-1427
 - b. 2-benzyl-4-chlorophenol: GDCI-62201-1354
 - c. Para tertiary amyl phenol: GDCI-064108-1461

You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI listed above, you may contact the Reevaluation Team Leader (Team 36): <http://www2.epa.gov/pesticide-contacts/contacts-office-pesticide-programs-antimicrobial-division>

3. Make the following label changes before you release the product for shipment:
 - Revise the EPA Registration Number to read, “EPA Reg. No. 211-65.”
4. Submit one copy of the final printed label for the record before you release the product for shipment.

Should you wish to add/retain a reference to the company’s website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product’s label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA’s Office of Enforcement and Compliance.

If you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records. Please also note that the record for this product currently contains the following CSFs:

- Basic CSF dated 11/05/2019

If you have any questions, please contact Jacqueline Hardy phone at 703.308.6416, or via email at Hardy.jacqueline@epa.gov.

Enclosure Stamped Label

(Administrative Note: The following text is required for all labeling, regardless of target market)

TRI-CEN

High pH Phenolic Sanitizer for Use Only in Pharmaceutical Cleanrooms

Formulated for Effective Aseptic Controlled Environment ("Clean Room") Sanitation

Active Ingredients

Ortho-benzyl-para-chlorophenol.....	4.21%
Orthophenyl-phenol.....	2.52%
Para tertiary amyl phenol.....	2.22%
Other Ingredients.....	91.14%
	100.00%

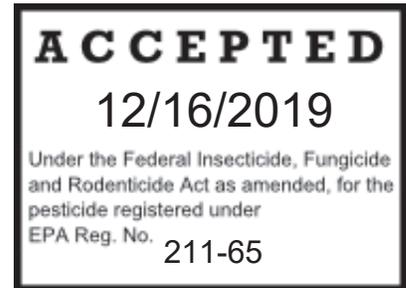
**KEEP OUT OF REACH OF CHILDREN
DANGER**

SEE BACK OR SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

Central Solutions, Inc.
PO Box 15276
401 Funston Road
Kansas City, KS 66115

EPA Reg. No. 211-XX
EPA Est. No. 211-KS-1

Net contents: (XX ounces) (x Gallons)



(Administrative Note: The following text is required for all labeling, regardless of target market)

FIRST AID	
If in eyes	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with plenty of water for 15-20 minutes.• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.• Call a poison control center or doctor for treatment advice.
If on skin or clothing	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15-20 minutes• Call a poison control center or doctor for treatment advice.
If inhaled	<ul style="list-style-type: none">• Move person to fresh air.• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.• Call a poison control center or doctor for further treatment advice.
If swallowed	<ul style="list-style-type: none">• Call a poison control center or doctor immediately for treatment advice.• Do not induce vomiting unless told to do so by a poison control center or doctor.• Do not give any liquid to this person.• Do not give anything by mouth to an unconscious person
HOTLINE NUMBER For emergency medical advice, call your local poison control center or a doctor Have the product container or label with you when seeking medical advice or treatment.	
NOTE TO PHYSICIAN Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression, and convulsion may be needed.	

Product Questions? Call 1-800-255-0262 during normal business hours (8am-5pmCST)

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

DANGER. Corrosive. Causes irreversible eye damage. Do not get in eyes or on clothing. Wear protective eyewear (goggles, face shield). Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse. Harmful if swallowed. Harmful if absorbed through skin. Avoid contact with skin, eyes, or clothing. Harmful if inhaled. Avoid breathing spray mist.

USER SAFETY REQUIREMENTS

Users must wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet. Users must remove PPE immediately after handling this product. Wash the outside of the gloves before removing. As soon as possible, wash thoroughly and change into clean clothing. Users must remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

PHYSICAL AND CHEMICAL HAZARDS

Combustible. Do not use or store the product near heat or open flame

(Use Environmental Hazards statement on containers containing ≥ 5 gallons of product):

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

PESTICIDE STORAGE - Store in a securely closed original container. Store in area that will prevent cross contamination of other pesticides, fertilizer, food, and feed. Avoid storage at temperature extremes or in sunlight.

PESTICIDE DISPOSAL - Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL

(Note to Reviewer: One or more of the following paragraphs for Container Handling will be selected, depending on packaging use/type.)

- Nonrefillable container. Do not reuse or refill this container.
Offer for recycling, if available.

or

Offer for reconditioning, if appropriate

Or

Puncture and dispose of in a sanitary landfill, or by incineration.

Less than or equal to 5 gallons:

Clean container promptly after emptying.

or

Triple rinse container (or equivalent) promptly after emptying.

Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container $\frac{1}{4}$ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.

Greater than 5 gallons:

Clean container promptly after emptying.

or

Triple rinse container (or equivalent) promptly after emptying.

Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container $\frac{1}{4}$ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times.

{For non-refillable SIMPLEMENTIX® 200 Liter Drums}

Non-Refillable Container. Do not reuse or refill this container. Completely empty container by running pump to dispense all product left in system into application equipment. Dispose of container by permitted onsite incinerator or by transport to offsite permitted incineration services.

If incineration is unavailable, fill the container $\frac{1}{4}$ full with water. Shake for 10 seconds. Empty and collect rinsate into appropriate storage vessel for disposal. Repeat this procedure two more times. Follow Pesticide Disposal instructions for rinsate disposal. Then offer for recycling or dispose of in a sanitary landfill.

(For other SIMPLEMENTIX® and F style containers 1 gallon or smaller that will be incinerated)

Completely empty container allowing the product to drain for 10 seconds after the flow begins to drip. Dispose of container by permitted onsite incinerator or by transport to offsite permitted incineration services.

If incineration is unavailable, fill the container 1/4 full with water. Shake for 10 seconds. Empty and collect rinsate into appropriate storage vessel for disposal. Repeat this procedure two more times. Follow Pesticide Disposal instructions for rinsate disposal. Then offer for recycling or dispose of in a sanitary landfill.

{Note to Reviewer: SIMPLEMENTIX[®] System Containers are designed to reduce worker and environmental exposure to the concentrate. These containers are designed for aseptic mixing and handling in clean rooms for closed system mixing within the container}

(Administrative Note: The following text is required for all containers destined for sale and/or distribution in the State of California):

["PROPOSITION 65 ICON"ATTENTION: This product contains a chemical known to the State of California to cause cancer"]

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

PELIGRO: Si no puede leer en ingles, pregunte a su supervisor sobre las instrucciones de su uso apropiadas antes de trabajar con este producto.

Non-Food Contact Sanitization: Pre-clean surface prior to sanitization. (Mix) (Prepare) (a)] 1 ounce) (of (this product) (product name)) per 1 gallon of water use solution (or equivalent use dilution) (solution according to SIMPLEMENTIX[®] System Container instructions)]. Apply use solution to hard nonporous (inanimate) (environmental) surfaces using a brush, sponge, cloth, mop, auto scrubber or mechanical spray device ((hand pump) coarse pump or trigger spray device) or by immersion so as to thoroughly wet surface. For sprayer applications, spray 6-8 inches from surface. Do not breathe spray. Rub with brush, cloth, or sponge. Allow surfaces to remain wet for 5 minutes. [(Rinse) (Wipe up excess liquid (with a paper towel)) (Allow to air dry)]. Change cloth, sponge or towels frequently to avoid redeposition of soil. [(Change the solution) (A fresh solution must be prepared) (Prepare a fresh solution)] at least daily or [(more often if use solution) (when use solution)] becomes visibly [(dirty) (soiled) (diluted)].

{or} [Add 1 ounce TRI-CEN to the gallon of water. Remove heavy soil or gross filth then apply solution with a mop, cloth, sponge, or hand pump trigger sprayer, so as to wet the surface thoroughly. Allow to remain wet for 5 minutes and then let air dry. If higher detergency is desired, increase dilution to 2 ounces per gallon of water. Prepare a fresh solution for each use.]

TRI-CEN is acceptable for use by pharmaceutical and biotechnology industries. For use on hard, inanimate surfaces in aseptic filling and gowning rooms, general manufacturing areas, or on machinery, tables, counters, laminar flow benches, floors, walls, stainless steel, glazed porcelain, glass, and chrome.

(Alternative label text for center panel):

Product and container sterilized and distributed by _____.

Sterile pharmaceutical clean room formula.

TRI-CEN is a phosphate free detergent

MARKETING CLAIMS AND STATEMENTS

TRI-CEN may be used on any hard, inanimate surfaces such as walls, floors, door handles, counter tops, table tops, sinks, waste containers, lockers, desks, and other hard, nonporous surfaces.

When used as directed, TRI-CEN may be used on hard, nonporous surfaces, materials, and components such as:
Metals: Stainless steel, chrome plated steel, brass, copper, & aluminum), Plastics: Fiberglas™, Formica™, nylon, ABS, Lexan™, Plexiglass™, acrylics and vinyl, glazed porcelain, glass, glazed ceramic tile, latex, enamel & epoxy painted surfaces, Vinyl, rubber, terrazzo, marble, glazed ceramic and quarry tile floor surfaces, Urethane, lacquer, and shellac wood finished surfaces, Other surfaces not harmed by water based cleaners.

TRI-CEN is an effective sanitizer on inanimate, non-porous non-food contact surfaces demonstrated in testing against *Staphylococcus aureus* (ATCC#6538) and *Klebsiella pneumoniae* (ATCC# 4352) in 5 minutes.

(Administrative Note: The following text is optional for labeling destined for the SIMPLEMIX® System Technology, closed system dilution mixing system.)

SIMPLEMIX® System Technology for closed system mixing of pre-measured concentrate and water. *{To be used on applicable container}*

SIMPLEMIX® use solution from pre-measured ingredients in this container. Accurate every time. *{To be used on applicable container}*

SIMPLEMIX® convenient self-contained mixing system for use solution without measuring. *{To be used on applicable container}*

SIMPLEMIX® (self-contained bottle/drum design holding pre-measured concentrate/water portions to yield, after mixing, exact use solution of a specified final volume.) *{To be used on applicable container}*

SIMPLEMIX® SYSTEM CONTAINER SYSTEM INSTRUCTIONS:

{Trigger Spray Bottle} lid label}

1. **To prepare use solution, open cap.**
2. Peel off inner seal by grasping tab at far edge and pulling off.
3. Firmly push small, inner container [(completely) (all the way)] down.
4. Replace cap and tighten.
5. Slowly swirl for 15 seconds.
6. Move spray nozzle to open position.
7. Follow directions for use on label.} or

{Gallon Size Bottle} lid label}

1. **To prepare use solution, open cap.**
2. Peel off inner seal by grasping tab at far edge and pulling off.
3. Firmly push small, inner container [(completely) (all the way)] down.
4. Replace cap and tighten.
5. Slowly swirl for 15 seconds.
6. Open small side spout and peel off inner seal, as above.
7. Pour solution from small side spout onto surfaces to be treated or alternate containers.
8. Follow directions for use on label.} or

{200 Liter Drum} lid label}

(Note: To be used with customer supplied pump.):

1. **Close all valves.**
2. Uncoil hoses.
3. Connect center hose to pump between X and Y.
4. Open valve 1, then valve 2, then valve 4
5. START pump to empty cubic container
6. When cubic container is empty, turn pump OFF.
7. Close valve 1 and valve 2.
8. Open valve 6 and valve 5.
9. Re-start pump and mix 15 minutes.
10. STOP pump.
11. Close valve 4.
12. To dispense - Open Valves 3 and 7. Run pump only when dispensing.
13. Follow directions for use on label.}

{Administrative Note: To appear as label end panel for customer use on containers; convenience item.}

User Information
Date Opened/Operator: <input type="text"/>
Expiration Date: <input type="text"/>
Area: <input type="text"/>

(Administrative Note to reviewer: Optional Visual to Ensure Customer Compliance with Directions)

{1 Gallon SimpleMix}



{16 Ounces SimpleMix}



{Administrative Note to Reviewer: Logo to appear on SIMPLEMENT SYSTEM packages.}

